FILED
NOV 30 1981
CLERK

Nos. 80-2182; 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

BRIEF FOR THE GENERIC PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

ALFRED B. ENGELBERG
Attorney for Amicus Curiae
90 Park Avenue
New York, New York 10016
(212) 697-5995

Of Counsel:

AMSTER, ROTHSTEIN & ENGELBERG

TABLE OF CONTENTS

	PAGE
I. Authority to File	1
II. Interest of Amicus Curiae	1
III. Summary of Argument	2
IV. Argument	5
A. The Factors Leading To The Adoption of State Substitution Laws Support The Trial Court's Decision	5
B. Cyclospasmol Has Become A Generic Term and Its Use At The Consumer Level Does Not Constitute Trademark Infringement	13
C. There Has Been No Contributory Infringement of the "Cyclospasmol" Trademark	17
D. The Establishment of a Monopoly Over The Color of a Drug Cannot Be Justified As A Matter of Law	19
E. The Labeling Requirements of State Substitution Laws Are Sufficient to Guard Against Acts of Unfair Competition	27
F. Conclusion	29

TABLE OF CASES

American Rolex Watch Corp. v. *Ricoh Time Corp.*, 491 F.2d 877 (2d Cir. 1974) 21

American Safety Table Company v. *Schreiber*, 269 F.2d 255 (2d Cir. 1959) 21

Bayer Co., Inc. v. *United Drug Co.*, 272 F. 505 (S.D. N.Y. 1921) 14, 15

PAGE

Beecham, Inc v. *Zenith Laboratories, Inc.*, Civil Action No. 81-1731 (D.N.J., October 22, 1981) 28

Biocraft Laboratories, Inc. v. *Merck & Co., Inc.*, Civil Action No. 77-693 (D.N.J., October 2, 1980) 19, 26

Boehringer-Ingelheim GmbH v. *Premo Pharmaceutical Laboratories, Inc.*, Civil Action No. 79-358 (D.N.J. September 24, 1980) 19, 24

Bose Corp. v. *Linear Design Labs Inc.*, 467 F.2d 304 (2d Cir. 1972) 21

Brulotte v. *Thys Co.*, 379 U.S. 29 (1964) 13

Carter-Wallace v. *United States*, 496 F.2d 535 (Ct. Cl. 1974) 11

Coca-Cola Co. v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (D.Mass. 1946), *aff'd* 162 F.2d 280 (1st Cir.), *cert. denied*, 322 U.S. 809 (1947) 17

Colligan v. *Activities Club of New York, Ltd.*, 442 F.2d 686 (2d Cir. 1981) 21

Compco v. *Day-Brite Lighting, Inc.*, 376 U.S. 239 (1964) 3, 21

Dawson Chemical Co. v. *Rohm Haas Co.*, 448 U.S. 176 (1980) 18

Application of Deister Concentrator Company, Inc., 289 F.2d 496 (C.C.P.A. 1961) 25

DuPont Cellophane Co. v. *Wax Products Co.*, 85 F.2d 75 (2d Cir. 1936) 14

Hoffman La Roche v. *Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980) 19

International Election Systems Corporation v. *Shoup*, 452 F.Supp. 684 (E.D. Pa. 1978), *aff'd without*

PAGE

opinion, 595 F.2d 1212 (3d Cir. 1979) 22

Ives Laboratories, Inc. v. *Darby Drug, Inc.*, 455 F. Supp. 939 (E.D.N.Y. 1978) 5

Ives Laboratories Inc. v. *Darby Drug, Inc.*, 488 F. Supp. 394 (E.D.N.Y. 1980) 28

Kellogg v. *National Biscuit Co.*, 305 U.S. 111 (1938) 3, 13, 14, 20, 21, 23

L'Aiglon Apparel v. *Lana Lobell, Inc.*, 214 F.2d 649 (3rd Cir. 1954) 21

Marion Laboratories, Inc. v. *Michigan Pharmacal Corp.*, 338 F. Supp. 762 (E.D. Mich. 1972) 19

Merrill-National Labs, Inc. v. *Zenith Labs., Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977) 19

Norwich Pharmacal v. *Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) 22

Pagliero v. *Wallace China Co.*, 198 F.2d 339 (9th Cir. 1952) 21

Penwalt Corp. v. *Zenith Labs., Inc.*, 472 F. Supp. 413 (E.D. Mich. 1979) 19

Pharmaceutical Society of N.Y. Inc. v. *Lefkowitz*, 454 F. Supp. 1175 (S.D.N.Y. 1978), *aff'd* 586 F.2d 953 (2d Cir. 1958) 11

Premo Pharmaceutical Laboratories, Inc. v. *United States*, 629 F.2d 795 (2d Cir. 1980) 29

A. H. Robins Co. v. *Medicine Chest Corp.*, 206 U.S. P.Q. 1015 (E.D. Mo. 1980) 19

Ross-Whitney Corp., et al. v. *Smith, Klein & French Laboratories*, 207 F.2d 190 (9th Cir. 1953) 20

PAGE

Saxlehner v. *Wagner*, 216 U.S. 375 (1910) 4, 12, 18, 20

Scott Paper Co. v. *Marcalus Mfg. Co.* 326 U.S. 249 (1945) 13

Sears Roebuck & Co v. *Stiffel Company*, 376 U.S. 225 (1964) 3, 13, 23

Singer Mfg. Co. v. *June Mfg. Co.*, 163 U.S. 169 (1896) 3, 13, 14, 20

Smith v. *Chanel, Inc.*, 402 F.2d 562 (9th Cir. 1968) 12

Smith, Klein & French Laboratories v. *Brouder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959) 20

Smith, Klein & French Laboratories v. *Clark & Clark*, 157 F.2d 725 (3d Cir. 1946) 19

SK&F Co. v. *Premo Pharmaceutical Labs*, 625 F.2d 1055 (3d Cir. 1980) 19

Societe Comptoir de L'Indus., Etc. v. *Alexander's Dept. Stores*, 299 F.2d 33 (2d Cir. 1962) 12

Upjohn Co. v. *Schwartz*, 246 F.2d 254 (2d Cir. 1957) 19

Virginia State Board Of Pharmacy v. *Virginia Citizens' Consumer Council*, 425 U.S. 748 (1976) .. 3, 5, 9, 23

Frederick Warne & Co. Inc. v. *Book Sales, Inc.*, 481 F. Supp. 1191 (S.D.N.Y. 1979) 22

Warner & Co. v. *Lilly & Co.*, 265 U.S. 526 (1924) ... 18, 19, 28

West Point Manufacturing Co. v. *Detroit Stamping Co.*, 222 F.2d 581 (6th Cir. 1955) 21

STATUTES PAGE

15 U.S.C. § 1114 4
15 U.S.C. § 1125(a) 21, 29
21 U.S.C. § 321 8
21 U.S.C. § 352 16
21 U.S.C. § 355 ..... 8, 29
N.Y. Educ. Law (McKinney's Supp. 1981):
§ 6810 11
§ 6815 11
§ 6816 ..... 11, 27
§ 6816-a 11
Wisc. Stat. Ann. § 450.075(4) 25

MISCELLANEOUS

Annual Prescription Survey by the Albany College of Pharmacy, *Medical Marketing and Media*, April, 1978 10
Consumer Reports, January 1975, at p. 52 ..... 9, 10
FDA Consumer Magazine, February 1979 9
FDA Consumer Magazine March, 1973 8
Multi-Source Drugs: An Acceleration in the Use of Lower-Costing Substitutes? *Reynolds Securities Information Report*, May 13, 1977 10
Patent Term Extension in the Pharmaceutical Industry, Office of Technology Assessment, July, 1981, at 33 10
Staff Report to the Federal Trade Commission, Drug Product Selection 96 (1979) 5, 7
The New England Journal of Medicine, April 13, 1978 10
Warner, Consumer Protection and Prescription Drugs: *The Generic Substitution Laws*, 67 Ky. L.J. 389 (1979) 12

Nos. 80-2182; 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERBY PHARMACEUTICAL CO., INC.,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

BRIEF FOR THE GENERIC PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

I. Authority to File

This Amicus Brief is presented to the Court under Rule 36.2 and letters of consent from Petitioners and Respondent are on file with the Clerk of the Court.

II. Interest of Amicus Curiae

The Generic Pharmaceutical Industry Association was formed in 1980 by a group of independent generic drug manufacturers, distributors and retailers to seek solutions to common problems having an economic impact on the distribution and sale of generic drugs. Many of these problems relate to the implementation of recently enacted laws in 49 states, the District of Columbia and Puerto Rico which are intended to encourage the substitution of lower cost, therapeutically equivalent generic drugs for unpatented higher priced, heavily promoted brand name drugs as a means of reducing health care costs. The

Association's member companies account for a substantial portion of the sales of independently manufactured generic prescription drugs.

The questions raised in this case transcend the specific petitioners and facts and have a direct economic impact on the generic pharmaceutical industry, government medical reimbursement programs and consumers of prescription drugs. Prior to the decision in the case under review and similar recent decisions in the Third Circuit, it was generally believed that the size, color and shape of prescription drugs were functional and could not be exclusively appropriated by a single manufacturer. Dozens of identically colored drugs made by different manufacturers have, in fact, coexisted in the marketplace for many years withot engendering any legal controversy. The recent decisions not only create uncertainty with regard to the status of those drugs but would eliminate the long accepted and common practice of making equivalent medications in the same colors in the future as patents covering other drugs expire. The members of Amicus are the actual and potential manufacturers of these drugs and will be economically affected by the Court's decision. Consumers will also be affected since the affirmance of the Second Circuit's decision would establish a substantial economic barrier to market entry of new generic drug products after the 17 year patent monopoly expires thereby adversely affecting the function and purpose of the State generic drug substitution laws.

III. Summary of Argument

The Second Circuit decision grants to the manufacturer of a patented drug a strict and perpetual monopoly after expiration of the patent in both the appearance of the drug and the name by which it has come to be commonly known by physicians and consumers. The immediate effect of that decision is to create by judicial action a national policy promoting high drug prices which threaten to force the poor and aged to choose between the allevia-

tion of physical pain and the enjoyment of basic necessities. See *Virginia State Board of Pharmacy* v. *Virginia Citizens' Consumer Council*, 425 U.S. 748, 754, 764 (1976). This novel judicially imposed policy decision directly conflicts with the legislatively established policy of essentially every State to mandate or strongly encourage the substitution of lower cost, therapeutically equivalent generic drugs in situations where the physician's prescription generically identifies the medication by referring to its brand name.

The State substitution laws were enacted after careful analysis of the manner in which prescription pharmaceuticals are dispensed and reflect a belief by the States that the *de facto* conversion of the brand name to a generic designation during the period of patent exclusivity directly contributes to inordinately high drug prices after expiration of the patent monopoly. The substitution laws reprenent State action in aid of the welfare of its citizens which should be given full respect by this Court, absent any conflicting and overriding Federal law or policy which mandates a contrary result. No such law or policy exists.

This Court has long recognized the inherent tension which exists between the monopoly created by the patent system and our system of free enterprise which encourages the unfettered copying of formerly patented products and has struck down every attempt to extend the length of the patent monopoly. *Kellogg* v. *National Biscuit Co.*, 305 U.S. 111, 120-122 (1938); *Singer Mfg. Co.* v. *June Mfg. Co.*, 163 U.S. 169, 185 (1896); *Sears, Roebuck & Co.* v. *Stiffel Company*, 376 U.S. 225, 230 (1964); *Compco* v. *Day-Brite Lighting, Inc.*, 376 U.S. 239 (1964). It has not permitted patent holders to perpetuate their monopolies by claiming exclusive rights in either the name or appearance by which the product was known to the public during the period of patent monopoly. The legitimate interest of the public in knowing the source of origin of the products which became available from multiple sources upon patent expiration has been recognized by this Court and protected by appropriate labeling requirements to prevent unfair competition.

The State substitution laws fully accomodate State and Federal principles of unfair competition by requiring pharmacists to label prescriptions as to source of origin when a generic substitute is dispensed. In New York a failure to adhere to labeling requirements may result in fines, imprisonment, and loss of license. Those seeking to bypass the law are being prosecuted.

The Second Circuit opinion fails to consider the inherent conflict between its decision and both the Federal policy prohibiting the extension of patent monopolies, and the State policy fostering substitution of generic drugs. It avoids that issue by limiting its holding to contributory infringement of the "Cyclospasmol" trademark under Section 32 of the Lanham Act 15 U.S.C. § 1114, and narrowly view this case as a matter arising under Federal trademark infringement law. It ignores the factual findings of the Trial Court, that there was no direct trademark infringement because the term "Cyclospasmol" had become the generic name of the medication at the consumer level and disregards the established line of authority going back to this Court's decision in *Saxlehner* v. *Wagner*, 216 U.S. 375, 380 (1910), which holds that there is no trademark infringement when a manufacturer refers to the trademark of a copied product for the purpose of telling the public what is being copied.

The Second Circuit's attempt to narrow the issue also side steps the Trial Court's factual finding that Respondent Ives failed to prove the color of "Cyclospasmol" had a secondary meaning, i.e., that it indicated a single, albeit anonymous, source of origin. The Circuit Court was duty bound to accept the Trial Court's finding of a failure of proof since it was not clearly erroneous. Accordingly, if the Second Circuit had considered all of the issues raised by the appeal, it would have been left in the anomolous position of enjoining the capsule color under Section 32, while simultaneously finding that the color did not indicate origin.

The Second Circuit opinion also disregarded the unique marketing environment of prescription pharmaceuticals

and failed to differentiate this case from every day shopping situations in which the consumer's purchasing decision may be unfairly influenced by too close a similarity in appearance of adjacently displayed products. Here, as a Federal Trade Commission study has aptly noted, the physician prescribes, the pharmacist dispenses, and the patient pays.[1] No advertising or promotional activities are directed at patients, and prescription drugs are not purchased by choice or on impulse. The average patient neither knows nor cares if the name or appearance of a medication is associated with a single producer. The patients care only that they receive the medication which their doctor prescribed and that it works for the purpose intended. The State substitution laws are, in essence, nothing more than a recognition of this fact.

This case represents an attempt to maintain a monopoly position by erecting new barriers to replace the brand name barrier, which has been somewhat lowered by the State substitution laws, and the price advertising barrier struck down by this Court in *Virginia State Board* v. *Virginia Citizens Consumer Council, supra.* A decision by this Court holding that there can be no monopaly over drug colors does not require this Court to create any exception to establish principles of law. To the contrary, it requires only the application of the principle of *stare decisis.*

IV. Argument

A. The Factors Leading To The Adoption of State Substitution Laws Support The Trial Court's Decision

The Trial Court's decision[2] denying Respondent Ives all relief was based on a number of clearly factual findings having a direct impact on whether the "Cyclospas-

---

[1] Staff report to the Federal Trade Commission, Drug Product Selection 96 (1979).

[2] *Ives Laboratores, Inc.* v. *Darby Drug, Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980).

mol" trademark was directly or contributorily infringed. The Court found that:

1. Respondent Ives was the sole source of the drug from 1962 until the patent covering the product expired in 1972. (455 F.Supp. at 939)

2. Because the drug may be dispensed only on prescription, Ives had not promoted its product to the general public but had spent in excess of Ten Million Dollars ($10,000,000) on advertising and promotion primarily to doctors. This promotion included the personal distribution of free samples and other materials by "detail men" who made numerous personal visits to physicians. (455 F. Supp. at 939; 488 F.Supp. at 396)

3. The proven incidents of mislabeling under the New York substitution law all arose in situations where the physician had prescribed the medication by using its brand name "Cyclospasmol" rather than a generic identifictaion. In the vast majority of cases, substitution occurred in accordance with the New York substitution law. Of the ten instances of such mislabeling actually established at trial, five involved the use of the word "generic" on the label as a modifier for "Cyclospasmol" and nine out of ten pharmacists informed the patient that a generic product had been dispensed. Such mislabeling as occurred stemmed from confusion as to the labeling requirements of the New York generic drug substitution law. (488 F.Supp. at 397, 398)

4. Surveys conducted by Ives demonstrated that a substantial number of patients who were taking "Cyclospasmol" were unable to associate that name or any other name with their medication, and there was no evidence that any of the survey respondents had ever heard of the drug by any name other than "Cyclospasmol" or that they supposed that "Cyclospasmol" was a brand name indicating the source of the drug. (488 F.Supp. at 400)

5. There is no reason to suppose that the word "Cyclospasmol" signifies a source of origin to patients since they have not been the target of sales compaigns and play no role in choosing what drug to buy. Nothing in the record suggests that to them the name signifies anything more than a kind of drug to which they have become habituated. (488 F.Supp. at 400)

6. If patients do not know that the word "Cyclospasmol" designates a single source, it logically follows that a color they associate with that name does not signify a single source to them. In any event, the color of the capsule has significant functional characteristics since it is relied on by patients, physicians and hospitals to identify the medication rather than its source, and any change in the color of a medication would cause confusion and anxiety. (488 F.Supp. at 398-400)

The foregoing factual findings are completely consistent with the rationale underlying the adoption of State substitution laws. Those substitution laws and the factors which led to their adoption are directly relevant here, since they are an essential part of the market environment in which the allegedly infringing acts occurred.

Subsequent to World War II, there was a large increase in the number of available prescription drug products and, accordingly, an increase in the reported instances of duplication and counterfeiting of such products. Some of these drugs were not as safe or effective as the brand name drugs they were imitating. Seizing on this problem, the major pharmaceutical manufacturers spearheaded a national effort which resulted in the passage of State "anti-substitution" laws. These laws prohibited the pharmacist from dispensing any product other than the product specifically identified on the prescription.[3] The

[3] FTC Staff Report, *supra*, note 1 at 146 et seq. The FTC Staff Report contains a thoroughly documented analysis of the role of the manufacturer, physician, pharmacist, patient and State and Federal regulation in the distribution and selection of prescription drugs and the impact of these factors on competition.

anti-substitution laws provided significant economic impetus to increasing emphasis by major pharmaceutical companies on promotional techniques designed to encourage brand name prescribing by physicians.

In 1962, Congress amended the Food, Drug and Cosmetic Act to include provisions requiring manufacturers of new drugs to establish, prior to marketing, that those drugs were safe and effective. See 21 U.S.C. § 321 et seq. The 1962 Amendments also provided for the reevaluation of the efficacy of products which had been approved for marketing between 1938 and 1962. 21 U.S.C. § 355. The FDA also established a code of good manufacturing practices to insure that all products were not only identical in their composition and therapeutic value, but were also safely manufactured.

By the late 1960's, it had become apparent that the amendments to the Food and Drug law were working in a manner which assured that approved generic drugs were equivalent to their brand name counterparts, and this fact began to be publicly expressed by the regulatory experts. For example, the Final Report of the Task Force on Prescription Drugs, U.S. Department of Health, Education and Welfare, February 7, 1969 reported:

> "On the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to public health."

In the ensuing years, similar statements, including the following, were made by FDA officials:

> "On the basis of data we have accrued to date, we cannot conclude that there is a sigificant difference in quality between the generic and brand-name products tested."[4]

---

[4] Dr. Henry F. Simmons, Director of FDA's Bureau of Drugs, *FDA Consumer Magazine*, March, 1973.

> "All drugs, whether they are sold under their brand names or their generic names, must meet the same FDA standards for safety, strength, purity and effectiveness. All drug manufacturers, big or small, are subject to FDA inspection and must follow the Agency's Current Good Manufacturing Practice Regulations. That is why FDA believes there is no significant difference in quality between generic and brand name drugs."[5]

The established equivalence of generic drugs should logically have led to an immediate and rapid expansion in the rate of sale of those products in view of their significantly lower cost to consumers. Numerous reported studies over the past ten years have documented the significantly lower cost of generic drugs and the savings which are realized on generic drug purchases.[6] This Court has taken notice of studies establishing price differentials of up to 1200% for the same amounts of a specific drug and concluded that "the phenomenon of widely varying drug prices is apparently national in scope."[7]

Despite the enormous price differentials, generic pharmaceutical products account for only a minute share of the prescription pharmaceutical market. There can be no doubt in this case that the use of the brand name (Cyclospasmol) as if it were the generic name (Cyclandalate) during the patent monoply period is directly responsible for that result. During the ten-year period from 1968 to 1977, only 10 to 14% of all new prescriptions were writen by physicians using the generic name of the medication, and that figure is inflated by a higher percentage of

---

[5] Annabel Hecht, FDA Office of Public Affairs, *FDA Consumer Magazine*, February, 1978.

[6] FTC Staff Report, *supra*, footnote 1, at 196-219; Consumer Reports, January, 1975, at p. 48.

[7] *Virginia State Board of Pharmacy* v. *Virginia Citizens' Consumer Council, Inc.*, *supra*, at 754.

generic prescriptions for certain antibiotics.[8] Prescriptions using the brand name rather than the generic name of the medication account for over 90% of the prescriptions of most drugs and, particularly, those drugs which were available from only a single source during the period when they were covered by unexpired patents. One recent study reports that twelve formerly patented drugs each retained more than a 90% share of the drugstore market and more than an 80% share of the hospital market, after the patents expired. Six of the drugs retained more than a 97% share of both markets.[9]

None of the foregoing statistics are particularly surprising in view of the vast promotional efforts of pharmaceutical firms which, as noted by the Trial Court in this case, ignore the consumer and are primarily directed at the prescribing physician. The drug industry spends an average of $4,000 to $5,000 annually per private practitioner.[10] The result of this exclusive brand name promotion during the period of the patent monopoly is to leave the patent holder with a continuing monopoly after the patent expires which is strong enough to limit effective price competition for prescription drugs. Indeed, the combination of lack of advertising at the consumer level and brand-name prescribing at the physician level, makes it highly unlikely that any consumer is ever actually exposed to the generic name of the product during the patent monopoly period, when the product is only available from a single source. It is not surprising, therefore, that widely prescribed medications such as Darvon, Valium and Librium, to name only a few ostensible trademarks,

---

[8] Annual Prescription Survey by the Albany College of Pharmacy, *Medical Marketing and Media*, April, 1978, at 24; Multi-Source Drugs: An Acceleration in the Use of Lower-Costing Substitutes? *Reynolds Securities Information Report*, May 13, 1977.

[9] Patent Term Extension in the Pharmaceutical Industry, Office of Technology Assessment, July, 1981, at 33.

[10] Donald Kennedy, Commissioner of Food and Drugs, *The New England Journal of Medicine*, April 13, 1978, at 846; *Consumer Reports*, January, 1975, at 52.

are actually household generic words and that consumers do not know or associate the names propoxyphene hydrochloride, diazepam or chlordiazepoxide HCL with these products, although they are, in fact, the true generic names.

It is against this backdrop, that the States, acting to protect the health and welfare of its citizens, have modified the anti-substitution laws and enacted laws which encourage the substitution of lower-cost therapeutically equivalent generic drugs for the brand name product actually set forth on a prescription.[11] This State policy is strongly reinforced by Federal policy. The Maximum Allowable Cost (MAC) Program instituted by the Department of Health, Education and Welfare limits third party reimbursement for prescription drugs under the Medicaid program to the lowest price at which a particular multi-source drug is generally available.[12] Other Federal agencies including the Veterans Administration, Department of Defense and Public Health Service have been buying lower-costing generic substitutes on a competitive bid basis for decades, even during the period when the originator's product was still covered by unexpired patents. *Carter-Wallace* v. *United States*, 496 F2d 535 (Ct. Cl. 1974).

Although the mechanics of the State substitution laws vary from State to State, they are all based on a common principle, namely, that the appearance of a brand name on a prescription does not automatically mean that the brand name product will be dispensed. Depending upon the requirements of a particular State, the physician must give some further indication that the use of the brand name was actually intended to command the pharmacist to dispense the brand name product and was not merely being used as a means of describing a type of medication, i.e., a generic use. The New York substitution law,[13] for ex-

---

[11] *Pharmaceutical Society of N.Y. Inc.* v. *Lefkowitz*, 454 F. Supp. 1175 (S.D.N.Y. 1978), *aff'd* 586 F2d 953 (2d Cir. 1958).

[12] FTC Staff Report, *supra*, footnote 1, at 134.

[13] N.Y. Educ. Law § 6810, 6815, 6816, 6816(a) (McKinney's Supp. 1981).

ample requires the prescription form to recite that it will be filled generically unless the doctor signs over the line stating "dispense as written". The other signature line which must appear on the form reads "substitution permissible, and a signature on that line permits the pharmacist to substitute a less expensive generic equivalent. Other State laws make substitution of a generic equivalent mandatory, unless the physician vetoes such substitution by writing the words "dispense as written", "do not substitute", or similar terminology on the prescription form.[14] Most of the State substitution laws also include provisions for determining what drugs may or may not be substituted; labeling requirements; and appropriate enforcement remedies to insure compliance with their provisions.

The State substitution laws are aimed squarely at the problem caused by brand name prescribing and have no application whatsoever to a generically written prescription since such a prescription clearly leaves specific drug product selection to the discretion of the pharmacist. It was because the States recognized that the average physician does not use and may not know the generic names, that the substitution laws were enacted.

The States were obviously mindful of the fact that the brand names are Federally registered trademarks and a broader use of them could not be authorized without creating a conflict with Federal trademark law. The substitution laws accordingly represent a State law codification of this Court's decision in *Saxlehner* v. *Wagner*, 216 U.S. 375 (1910), and the cases which have adopted its compelling logic. See *Societe Comptoir de L' Indus., Etc.* v. *Alexander's Dept. Stores*, 299 F2d 33 (2d Cir. 1962); *Smith* v. *Chanel, Inc.*, 402 F2d 562 (9th Cir. 1968). Those cases make it clear that a manufacturer who exercises the free enterprise right to copy an unpatented product also has a right to refer to the competitor's trade-

---

[14] See Warner, Consumer Protection and Prescription Drugs: The Generic Substitution Laws, 67 Ky. L. J. 389 (1979) for an excellent discussion of the specific provisions of State substitution laws and the differences between individual States.

mark in order to truthfully inform the public that his product is a copy. If this were not the case there would be no way of informing potential buyers that a product was, in fact, a copy. The State substitution laws do no more than permit a physician to refer to a trademark as a means to convey instructions to the pharmacist that a product equivalent to the product bearing the brand name be dispensed.

B. Cyclospasmol Has Become A Generic Term and Its Use At The Consumer Level Does Not Constitute Trademark Infringement

Although the State substitution laws represent an attempt to nibble at the edges of Respondent Ives' continuing monopoly after the patent expires, they can never be wholly effective for their intended purpose given the entrenchment of the brand name in the physicians' mind and the limitations on State action imposed by Federal trademark laws. But this Court has already defined a more direct method for preventing the perpetuation of brand name monopoly power created during the term of a patent. In both *Singer Mfg. Co.* v. *June Mfg. Co.*, 163 U.S. 169 (1885) and *Kellogg Company* v. *National Biscuit Company*, 305 U.S. 111 (1938), this Court held that upon the expiration of a patent, the name by which the patented article came to be known during the patent monopoly period passed to the public along with the right to make the article.[15] As the Court stated in *Singer:*

> "To say otherwise would be to hold that, although the public had acquired the device covered by the patent, yet the owner of the patent or the manufacturer of the patented thing had retained the designated name which was essentially necessary to vest the public with the full enjoyment of that which had be-

---

[15] This Court has consistently resisted all attempts to extend the patent monopoly beyond its expiration date by any technique. *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249 (1945); *Brulotte* v. *Thys Co.*, 379 U.S. 29 (1964); *Sears, Roebuck & Co.* v. *Stiffel Company, supra.*

come theirs by the disappearance of the monopoly." Id. 163 U.S. at 186.

In *Singer* this rationale was applied to the name "Singer" even though it was the surname of the manufacturer, because the patented sewing machines had come to be identified by that generic name and not by the generic name "sewing machines" during the patent monopoly period.

Respondent Ives may argue that the rationale of *Kellogg* and *Singer* cannot apply here because "Cyclospasmol" has an "official" generic name (Cyclandalate) which is designated by the "USAN and the USP Dictionary of Drug Names" and is therefore not the name by which the patented product came to be known during the patent period. Such an argument cannot obscure the fact that the general public neither knows nor cares about the official name of the product set forth in a technical dictionary to which it has no occasion to refer. The plain fact is that the only name which was ever exposed to consumer view was "Cyclospasmol" and this was due to the deliberate promotional activity of Respondent Ives at the physician level, while simulataneously refraining from promotion at the consumer level. Ives has maintained a substantial monopoly over prices and competition since the "Cyclospasmol" patent expired due to its continuing monopoly over the only name by which the drug was known. The relinquishment of the name "Cyclospasmol" is essentially necessary to vest the public with the full enjoyment of the expired patent monopoly.

There is an independent line of precedent which leads to the conclusion that "Cyclospasmol" has become a generic designation at the consumer level. *Bayer Co., Inc.* v. *United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921). See also *DuPont Cellophane Co.* v. *Wax Products Co.*, 85 F2d 75 (2d Cir. 1936). In *Bayer*, based upon marketing practices virtually indistinguishable from those found by the Trial Court with respect to "Cyclospasmol", Judge Learned Hand held that "Aspirin" had become a generic name since

it failed to convey to consumers that products bearing that name identified a single, albeit anonymous, source of origin. The Trial Court quite properly paraphrased Judge Hand in finding: (488 F.Supp. at 400)

> "No doubt to physicians and pharmacists the word "Cyclospasmol" signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaigns, and they play no role in choosing what drugs to buy. Nothing in the records suggest that they 'understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated.' [citing *Bayer* at 510]. Such patients as read their prescriptions do not attribute to "Cyclospasmol" 'any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue.' Id."

That Cyclospasmol has become generic at the consumer level[16] is further supported here by several facts which were not present in *Bayer*. First, in half of the mislabeling instances from Respondent Ives' shopping survey, under the New York substitution law, the pharmacist used the word "generic" or an abreviation thereof in conjunction with "Cyclospasmol", and in nine out of the ten instances the patient was informed that a generic substitute was being dispensed. These facts demonstrate that the word "Cyclospasmol" was being used generically, and there was no trademark infringement even if there was a failure to fully comply with the labeling requirements of the State substitution law. Second, during the years in which Ives was the sole source of "Cyclospasmol", the anti-substitution laws were in effect and brand name prescribing was dominant, thereby assuring that consumers would not be exposed to any other name for the product.

---

[16] This conclusion, which is supported by the Trial Court's findings, would not invalidate the Federal trademark registration owned by Ives but would limit its enforceability to infringement at the physician and pharmacist level as in *Bayer*.

Third, the nature of the word "Cyclospasmol" is such that it is highly suggestive, if not merely descriptive of the medication. Indeed, in the arguments submitted by Ives to obtain its Federal trademark registration, Ives acknowledged that the "Spasmol" suffix was descriptive of the spasmolytic properties of the medication and "carries in itself no significance as to the origin of the goods." Ives also argued that the products to which the name would be applied "by their very nature and purpose are likely to be known only to the drug trade and the medical profession and to be purchased and used only on the prescription of a physician and under his direction.'"[17]

The State substitution laws demonstrate a belief on the part of the 51 legislatures which studied the problem and enacted such laws that the brand names of prescription pharmaceuticals are the common designation by which drugs are known. Federal legislation has also recognized the fact that brand names tend to function as the generic name of the product. The 1962 Amendments to the Food, Drug and Cosmetic Act included a requirement that advertisements or other printed matter issued by drug manufacturers include the generic name of the product in type at least half as large as the brand name. 21 U.S.S. § 352. But such printed material never reaches the consumer, and the physician is obviously converted to essentially exclusive use of the brand name by heavy promotion. The plain fact is that the studies conducted more than fifteen years after enactment of these statutes establish that over 90% of prescriptions are written by brand name, even after the patents covering those prescription drugs have expired.

The owner of a patent covering a prescription drug has an ample opportunity during the period of patent exclusivity to develop both a generic product identification and a trade mark identification and to encourage the use of both by physicians and pharmacists. If that is done, the good will associated with the medication will pass into the

---

[17] United States Patent and Trademark Office, File History of U.S. Registration No. 602,919.

public domain when the patent expires and the good will associated with the trademark and the established experience and reputation of the original manufacturer will provide a fair competitive advantage without interfering with competition. The facts in this case unequivocally establish that this has not occurred and that the continuing monopoly over the name by which the medication has become known creates an unwarranted perpetual monopoly.

C. There Has Been No Contributory Infringement of the "Cyclospasmol" Trademark

In the absence of direct infringement, there can be no contributory infringement, and the Trial Court's finding that "Cyclospasmol" is a generic term at the consumer level eliminates the charge of trademark infringement under Section 32 of the Lanham Act. However, even if direct infringement exists, the evidence does not logically or legally support the conclusion that the acts of Petitioners contributed to that infringement.

The Second Circuit held that the criteria for the application of the doctrine of contributory infringement are set forth in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D.Mass. 1946) *aff'd* 162 F2d 280 (1st Cir.) *cert. denied* 322 U.S. 809 (1947). In so holding, the Second Circuit failed to consider whether there was any causal connection between the acts of Petitioners in selling their products to the pharmacist and the acts of the pharmacists in dispensing and labeling those products.

Snow Crest did not involve State laws permitting or encouraging prescription drug substitution. Accordingly, in that case any express or implied suggestion to the retailer that one product be substituted for another could only have been made in aid of an act of unfair competition. Under those circumstances, there was every reason to hold the manufacturer jointly liable with the retailer for the "passing off" which occurred as a result of their joint action. Here, the State substitution laws makes it perfectly permissible for the manufacturer's product to be legally substituted for the brand name product. Ac-

cordingly, a suggestion by a generic drug manufacturer that its product can be substituted for the brand name product does no more than promote the aims of State law designed to lower the patient's drug costs. The comparative advertising engaged in by Petitioners did precisely that in a manner which has long been approved. *Saxlehner* v. *Wagner, supra.* Moreover, the evidence in this record establishes that Petitioners' identically colored product was used for lawful substitution in the overwhelming majority of cases where it was dispensed. These facts undermine the finding that any causal link exists between the color of the products and any wrongful use of the word "Cyclospasmol" by the pharmacist.

Given the substantial legal use to which Petitioners' generic drug product could and was put as a matter of State law and policy, it was incumbent on Respondent Ives to prove not merely that Petitioners had suggested substitution, but that they had expressly or impliedly promoted *illegal* substitution. This distinction, which exists in other areas of intellectual property law was not recognized by the Second Circuit. For example, contributory infringement of a patent will not be found to exist unless the product sold is especially adapted for use in an infringing situation and has no substantial non-infringing use, unless, of course, the infringement is actively induced by the manufacturer. 35 U.S.C. § 271(b), (c); *Dawson Chemical Co.* v. *Rohm Haas Co.*, 448 U.S. 176 (1980). The drugs sold by Petitioners have a very substantial State protected non-infringing use namely, as lawful substitutes. Furthermore, the Trial Court here made a factual finding that there is no evidence to support the proposition that Petitioners, directly or by implication, suggested that pharmacists engage in acts of mislabeling or substitution which are illegal under New York State law and which could result in fines, imprisonment, and loss of license.

A causal link must also be established between the alleged acts of infringement and the relief awarded to prevent their continuance. In that regard, the decision of this Court in *Warner & Co.* v. *Lilly & Co.*, 265 U.S. 526

(1924) is far more relevant than the *Snow Crest* rationale on which the Second Circuit relied. The basic facts in *Warner* are essentially identical to those involved here, in that an identically colored pharmaceutical product was involved. There, although this Court found that substitution was improperly suggested by the distributor, it limited relief to labeling of the product with affirmative warnings against substitution, and did not enjoin the continued sale of the identically appearing product. It is of more than passing interest that no State substitution laws existed at the time *Warner* was decided by this Court.

D. The Establishment of a Monopoly Over The Color of a Drug Cannot Be Justified As A Matter of Law

Until the recent group of decisions barring the generic drug manufacturer from selling identically colored pharmaceutical capsules[18], the cases dealing with drug products uniformly rejected the attempts to enjoin the use of the same color, even in instances where there was evidence to establish acts amounting to wrongful substitution or passing off at the consumer level. *Warner & Co.* v. *Lilly & Co., supra; Norwich Pharmacal* v. *Sterling Drug, Inc.*, 271 F2d 569 (2d Cir. 1959), *cert. denied* 362 U.S. 919 (1960); *Upjohn Co.* v. *Schwartz*, 246 F2d 254 (2d Cir. 1957); *Smith, Klein & French Laboratories* v. *Clark & Clark*,, 157 F2d 725 (3rd Cir. 1946); *Marion Laboratories, Inc.* v. *Michigan Phar-*

---

[18] *SK&F Co. Premo Pharmaceutical Lab*, 625 F2d 1055 (3rd Cir. 1980); *Merrill-National Labs, Inc.* v. *Zenith Labs, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977); *Pennwalt Corp.* v. *Zenith Labs, Inc.*, 472 F.Supp. 413 (E.D. Mich. 1979); *A. H. Robins Co.* v. *Medicine Chest Corp.*, 206 U.S.P.Q. 1015 (E.D. Mo. 1980); *Hoffman La Roche* v. *Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980); *Boehringer-Ingelheim GmbH* v. *Premo Pharmaceutical Laboratories*, Civil Action No. 79-358, District of New Jersey, Memorandum Opinion, September 24, 1980; *Biocraft Laboratories, Inc.* v. *Merck & Co., Inc.*, Civil Action No. 77-693 District of New Jersey, Memorandum Opinion, October 2, 1980.

macal Corp., 338 F.Supp. 762 (E.D. Mich. 1972).[19] In each of the foregoing cases where relief was granted, relief was limited to some form of labeling or notice which would serve to prevent the drug in question from being passed off as the product of the original manufacturer.

The reasons why relief was totally barred or severely limited in the foregoing cases are succinctly set forth in this Court's decisions in *Sears* and *Compco*. Those decisions, however, did not establish any new unfair competition law, but merely held that the fundamental concepts with respect to the interface between unfair competition and free competition expresed in earlier cases preempted any contrary State laws. It was already long established by this Court's decisions in *Singer Mfg. Co.* v. *June Mfg. Co., supra; Kellogg Company* v. *National Biscuit Company, supra;* and *Saxlehner* v. *Wagner, supra,* that a product which is in the public domain can be freely copied by anyone and that the right to copy not only includes the right to call a product by its generic designation, but even to refer to the originator's trademark as a means of informing the public as to what is being copied. Unfair competition occurs only when a competitor attempts to sell a product in a manner which confuses the public as to the source of origin of the product. The most deliberate form of such confusion is the "passing off" of the product of one manufacturer as that of another without informing the purchaser. But even in such a case, the relief will be limited to prevention of the passing off and not the copying. As this Court stated in *Kellogg:*

> "Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds

---

[19] The only pharmaceutical product cases found in which the appearance of the product was actually enjoined are the Dexadrine cases, *Ross-Whitney Corp., et al.* v. *Smith Klein & French Laboratories*, 207 F2d 190 (9th Cir. 1953); *Smith, Klein & French Laboratories* v. *Brouder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959). However, both of those cases involved a unique pill shape in addition to the color.

> of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. Kellogg Company was free to use the pillow shaped form, subject only to the obligation to identify its product lest it be mistaken for that of the plaintiff." 305 U.S., at 120.

Similarly, in applying the foregoing principles, this Court in *Compco* concluded that a feature of a product (decorative ribbing on a light fixture) could be freely copied by anyone, even though that feature had acquired a "secondary meaning", and State law could do no more than provide for appropriate labeling as to source of origin in order to prevent passing off.[20]

The authorities also uniformly hold that the definition of what may be considered "functional" is extremely broad and extends not only to those features of a product having a useful purpose but also to any feature which is important to the commercial success of the product. *West Point Manufacturing Co.* v. *Detroit Stamping Co.*, 222 F2d 581 (6th Cir. 1955); *Pagliero* v. *Wallace China Co.*, 198 F2d 339 (9th Cir. 1952). See also *American Safety Table Company* v. *Schreiber*, 269 F2d 255 (2d Cir. 1959). Moreover, irrespective of such distinctions as can be drawn between so-called "functional" and "non-functional" features, the party seeking to enjoin the use of either has the burden of proving that the feature has

---

[20] The argument that *Sears* is a State law preemption case and does not apply to § 43 of the Lanham Act (15 U.S.C. 1125(a)) leads nowhere. There is nothing in either the language or legislative history of § 43(a) which would indicate a congressional intent to deviate from the principles expressed in *Kellogg*. See *L'Aiglon Apparel* v. *Lana Lobell, Inc.*, 214 F2d 649 (3rd Cir. 1954); *Colligan* v. *Activities Club of New York Ltd.*, 442 F2d 686 (2d Cir. 1981). Indeed, until this case, the Second Circuit has refused to extend § 43(a) to product features relying on this Court's opinion in *Sears* as establishing that proper labeling is sufficient relief. *Bose Corporation* v. *Linear Design Labs, Inc.*, 467 F2d 304, 309 (2d Cir. 1972); *American Rolex Watch Corp.* v. *Ricoh Time Corp.*, 491 F2d 877 (2d Cir. 1974).

acquired secondary meaning, i.e., that it has origin-indicating significance. *Norwich Pharmacal Company* v. *Sterling Drug, Inc., supra,* at 571; *Frederick Warne & Co., Inc.* v. *Book Sales, Inc.,* 481 F.Supp. 1191, 1195 (S.D.N.Y. 1979); *International Election Systems Corporation* v. *Shoup,* 452 F.Supp. 684, 710 (E.D. Pa. 1978).

Obviously, in all but the most exceptional circumstances, injunctive relief will not be granted which encroaches upon the right to copy products in the public domain. It will not be granted at all if the feature has functional attributes, in the broad sense of the term, irrespective of secondary meaning, and also will not be granted if secondary meaning is not proved, irrespective of functionality. It is for this reason that the prior decisions of this Court and others involving the color of drug products have uniformly refused to enjoin copying and have limited the relief granted to some form of labeling or identification.

The Second Circuit's opinion does not even deal with the topic of secondary meaning and disregards the Trial Court's specific finding that Respondent Ives failed to prove secondary meaning. That finding was supported by substantial evidence and was not clearly erroneous. Indeed, the Trial Court specifically found that Ives' survey was flawed and failed to even show that patients associated the name "Cyclospasmol" with a single source, let alone the color of the product. Moreover, to the extent that the Second Circuit's opinion can be interpreted as implicitly dealing with the question of secondary meaning, it erroneously shifted the burden of proof on that issue to Petitioners. Thus, its analysis of the color issue begins with the following statement:

> "Appellees have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically colored, look alike cyclandalate capsules instead of capsules of a different color, size or

shape which would minimize the practice of mislabeling, illegal substitution or confusion.'"[21]

But Petitioners have offered the most persuasive reason. They wish to copy a product on which the patent has expired. The burden is on Ives to establish a substantial reason why petitioners should not be permitted to engage in this act of free competition.

The Second Circuit opinion also erroneously reverses the standard to be applied in assessing the functionality of the drug color. The Triaal Court found, based on expert testimony, that elderly patients associate the appearance of their medication with its therapeutic effect and would suffer confusion and anxiety if the color of their medication were changed;[22] that patients comingle drugs in a single container and then rely on the appearance of the drugs to determine which medication to take; that color has some utility to doctors in hospital emergency rooms as a means of drug identification; and that color is a factor in the purchase decisions of hospitals, pharmacies and wholesalers in the light of the potential for confusion of medications. Many of these findings are reinforced by the actions of Respondent Ives and others who claim rights in drug colors. If coolor was truly intended to designate origin rather than product, it would obviously make more sense for each company to use the same color for all of its products rather than a different color for

---

[21] The decisions in New Jersey cited in footnote 18, *supra*, take an even more direct and equally erroneous approach and hold that proof of copying raises a strong, if not irrebuttal, presumption of secondary meaning thereby shifting the burden of proof to the copyist. This concept which is derived from cases involving packaging simulation is totally inapplicable to a product configuration case in view of *Kellogg*, *Sears* and the other authorities discussed herein.

[22] In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, *supra*, at 763 ,this Court took note of the significantly higher rate of chronic illness among the aged and the resulting higher level of drug expenditures by this group.

each product and even each dosage of the same medication. Nor would there be any reason to include a Product Identification Section in the industry sponsored Physicians Desk Reference which includes color photographs to help doctors identify each drug. These telltale signs of the utility and functionality of drug colors cannot be swept away on the ground that the initial color selection was arbitrary and any color could have been used, although that is precisely the position taken in many of the recent decisions. It seems highly unlikely that the same logic would be applied to a traffic light or a fire engine although the initial selection of their colors was also a matter of arbitrary choice.

The Second Circuit opinion does not and could not wholly refute the clear factual findings regarding functionaltiy but, rather, concludes that it is preferable to have the medical and pharmaceutical communities reeducate patients who suffer confusion or anxiety as a result of purchasing a lower cost generic drug of a different color rather than to permit Petitioners to continue selling an identically colored product.[23] In reaching this conclusion, the Second Circuit not only imposes a form of penalty on those who desire to purchase a less expensive prescription drug, but also reverses the balancing of interests defined by the prevalent authorities. As the Court of Customs and Patent Appeals has stated in construing *Kellogg* and a number of other decisions relating to attempts to monopolize product features:

> "The true basis of such holdings is not that they [product features] cannot or do not indicate source to the purchasing public but that there is an overriding public policy of preventing their monopolization, of preserving the public right to copy. A certain amount of purchaser confusion may even be tolerated in order

---

[23] Precisely the same logic has been applied in the New Jersey cases. See, e.g., *Boehringer-Ingelheim GmbH* v. *Premo Pharmaceutical Laboratories, supra,* footnote 18.

to give the public the advantages of free competition. *Application of Deister Concentrator Company, Inc.*, 289 F2d 496, 504 (C.C.P.A. 1961).

Insofar as the record is concerned, it is not even established that patients are being asked to tolerate any confusion. No claim is made that the consumers in Respondent Ives' shopping survey received the wrong medication or that patients were unable to determine the identity of the manufacturer of their medication. Rather, the evidence merely shows that the word "Cyclospasmol", in some form, appeared on the label, even though in nine out of the ten instances the patient was informed that a generic substitute was being dispensed. These facts cannot be equated with consumer confusion since, in the unique circumstances under which prescription drugs are dispensed, the patient's primary concern is in receiving the medication which the doctor prescribed, and there is no reason to suppose that the patient knows or really cares about the source of origin of the drug.

On the other hand, the evidence of functionality, even as construed by the Second Circuit, at least establishes that the color of the medication is an important ingredient in free competition in addition to having independent utility. It takes little imagination to recognize that doctors and pharmacists would avoid prescribing or dispensing more than one color of a particular medication in order to conserve their own time rather than the patients' money and to avoid unnecessary confusion or anxiety for older and infirm patients. Moreover, the suggestion that patients can be re-educated to a new color fails to explain how this re-education would work in a practical environment, e.g., when the newly colored medication is dispensed to a hospital patient by a nurse's aide and no doctor or pharmacist is immediately available to reassure the patient that a mistake is not being made. The obvious answer to this dilemma is that a hospital is not likely to stock multiple colors of the same medication, and the Trial Court so found based

on undisputed evidence.[24] The problem which would be caused by dissimilarly colored medications has also been recognized in at least one State substitution law which requires that refill prescriptions be refilled only with the same drug product used to fill the original prescription. *Wisconsin Statutes Annotated* § *450.075(4)*.

All of the foregoing establishes beyond significant doubt that an injunction barring a generic drug manufacturer from distributing an identically colored version of a therapeutically equivalent medication will interfere with free competition with respect to a product on which the patent monopoly has expired. If color is enjoined, generic drug manufacturers will be foreclosed from a substantial segment of the market, both by doctors who veto substitution to avoid a color problem and hospitals which limit purchases to a single color. Such an injunction would contravene this Court's decision in *Kellogg* and the long line of cases which have since applied its compelling logic.

The Second Circuit opinion seeks to minimize the actual impact which an injunction against color would have on competition by noting that some major pharmaceutical companies are now engaged in the manufacture of so-called "branded generics" in colors which differ from the formerly patented medication. The trial record establishes that these products were only recently introduced by these companies as a response to the State substitution laws and sell at a price which is lower than the original medication but significantly higher than the true generic substitutes involved in this litigation. The makers of

---

[24] Further evidence of the impact of color on hospital purchases may be found in *Biocraft Laboratories, Inc.* v. *Merck & Co., Inc.*, Civil Action No. 77-693 (District of New Jersey, Memorandum Opinion, October 2, 1980). The evidence considered by the Court in the Motion for Summary Judgment in that case included advertisements and promotional activities by Merck strongly urging that a switch to a differently colored medication would cause confusion of both patients and hospital staff. These ads were designed to frustrate competition from a differently colored medication being offered by another company.

branded generics still employ "detail men" who personally visit doctors and pharmacists for the purpose of persuading them that their higher priced products should be selected as substitutes in those instances where the State substitution law does not require that the lowest price generic drug be substituted. Obviously, only those companies having the sales force and financial resources to engage in the expensive promotion required to gain a foothold in the "branded generics" market and who have well known company names can compete in that fashion.

In relying on the existence of this new type of marketing practice as justifying an injunction against identically colored medications, Respondent Ives places economic barriers on the meaning of free competition which were clearly not contemplated by *Kellogg*. The issue here is not whether it would be possible for a potential new competitor to penetrate the market for a drug product on which the patent had expired by spending enough time and money to create a demand for a generic drug of a different appearance. The issue is solely whether the law requires the newcomer to do so when the appearance of the previously patented product has functional attributes and has not established secondary meaning to patients.

E. The Labeling Requirements of State Substitution Laws Are Sufficient to Guard Against Acts of Unfair Competition

Each of the State substitution laws contains provisions for labeling the prescription container with information with respect to the name of the drug and the source of origin of the drug, and penalties to ensure compliance with these requirements. In the State of New York mislabeling is a misdemeanor, and multiple violations of the labeling requirements will result in fines, imprisonment and the loss of license to engage in dispensing prescription pharmaceuticals.[25] These provisions are being enforced. As the Second Circuit noted (for a different reason), a

---

[25] New York Education Law § 6816 (McKinney's 1981 Supp.).

substantial number of indictments have been handed down in the course of enforcement of the New York labeling law.

There is no reason to suppose that there will be widespread violation of these State laws by pharmacists. As this Court noted in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc., supra,* at 768, high professional standards, to a substantial extent, are guaranteed by the close regulation to which pharmacists are subject, and pharmacists who are guilty of professional dereliction that actually endangers their customers will promptly lose their licenses.

The labeling requirements of the New York substitution law are clearly more stringent and carry higher penalties than the type of labeling relief normally accorded in cases of this kind. See *Warner* v. *Lilly, supra,* at 533; *Upjohn Company* v. *Schwartz, supra,* at 262. Moreover, additional labeling possibilities are available. At least one of the present Petitioners has offered to print its name on each capsule and that practice is becoming much more widespread in the generic pharmaceutical industry in those instances where it is possible to do so.[26]

Although the present case does not involve a therapeutically non-equivalent product, such products have been involved in some of the recent cases and, understandably, may have influenced the lower court decisions to enjoin color simulation.[27] However, an injunction against color is not necessary to remove such therapeutically non-equivalent drugs from the market. They are subject to re-

---

[26] *Ives Laboratoires, Inc.* v. *Darby Drug Co.,* 455 F.Supp. 939, 941.

[27] In *Beacham, Inc.* v. *Zenith Labs., Inc.,* Civil Action No. 81-1731 (District of New Jersey, Beach Decision, October 22, 1981) the Court denied a preliminary injunction on an identically colored but therapuetically equivalent drug and applied standards with respect to plaintiff's burden of proving secondary meaning which are consistent with the Trial Court's decision in this case.

moval by the FDA. 21 U.S.C. § 355; *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F2d 795 (2d Cir. 1980). Moreover, the distribution of an identically colored medication which is not therapeutically equivalent could be construed as carrying with it a false representation with respect to the nature of the product and, therefore, be subject to an injunction under § 43(a) of the Lanham Act. 15 U.S.C. § 1125(a).

Any or all of the foregoing remedies, or other similar labeling or notice provisions, will clearly serve the purpose of preventing unfair competition while perserving free competition in precisely the fashion contemplated by long-established public policy.

F. Conclusion

This Court is not being asked to legislate a solution to the problems involved in the distribution system for prescription drugs, or to create an exception to the law because of the substantial public interest involved. To the contrary, the proper resolution of this case requires nothing more than the application of the doctrine of *stare decisis* to a consistent line of decisions covering a span of almost a century. In applying that doctrine, this Court will also be giving substantial reinforcement to the policy underlying legislation enacted by the States in their traditional role of protecting the health and welfare of their citizens.

Respectfully submitted,

ALFRED B. ENGELBERG
Attorney for Amicus Curiae
90 Park Avenue
New York, New York 10016
(212) 697-5995

Of Counsel:

AMSTER, ROTHSTEIN & ENGELBERG